

REMARKS/ARGUMENTS

This is in response to the Office Action dated October 27, 2010. Claims 1-5, 7, 9-13, 15 and 21-23 are pending in the current application.

Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorensen et al. (US 4,231,369) in view of Kishi (JP 63-280013). The Examiner states it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an adhesive composition useful for medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as taught by Sorensen, and replace one of the hydrocolloids in the hydrocolloid phase with 3-40% of cyclodextrin and apply the composition on a polyester substrate as taught by Kishi.

The Examiner has the burden under 35 U.S.C. §103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Three criteria must be satisfied to establish a *prima facie* case of obviousness. First, the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would teach, suggest, or motivate one to modify a reference or to combine the teachings of multiple references. *Id.* Second, the prior art can be modified or combined only so long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Third, the prior art reference or combined prior art references must teach or suggest all of the claim limitations. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

Here, Applicant disagrees with the Examiner's assertion that the combination of references discloses that the **discontinuous** phase comprises 0.1 to 65wt% based on the total composition, of hydrocolloid composition comprising an uncomplexed cyclodextrin and a hydrocolloid other than cyclodextrin. The Examiner states on page 4 of the Office Action that Sorenson discloses a hydrocolloid disperse in a continuous phase , ie forming discontinuous phase and cites to the abstract, col. 4, lines 30-

31, 55-60 of Sorensen for support. Applicant asserts that these citations of Sorensen fail to disclose wherein a hydrocolloid composition comprising an uncomplexed cyclodextrin and a hydrocolloid other than cyclodextrin dispersed within a discontinuous phase of absorbent material [page 1 of the present invention]. The present invention more specifically discloses that hydrocolloid adhesives generally have two phases a rubbery phase and a **discontinuous phase of absorbent material** [page 1]. In the present invention, a hydrocolloid composition is dispersed within the discontinuous phase of the continuous phase. While Sorensen acknowledges a continuous phase, Applicant respectfully asserts it cannot be assumed that because of the disclosure of a continuous phase a hydrocolloid composition is dispersed within the discontinuous phase of a continuous phase. Sorensen specifically discloses that the hydrocolloids are distributed as particles in the **continuous** “rubber” like phase of the gel-like composition [column 4, lines 57-59]. Sorensen further discloses “to be required for a proper function as described above are retained in a rubber like composition having a hydrocolloid dispersed therein” [column 4, lines 61-63]. This citation relied upon by the Examiner does not teach or suggest that the hydrocolloid composition is retained in a discontinuous phase of absorbent material of the continuous phase. Rather, Sorensen discloses that the hydrocolloids are in the continuous rubbery phase which teaches against that of the present invention.

Kishi fails to remedy the deficiencies of Sorensen and fails to disclose wherein a discontinuous phase comprises a hydrocolloid composition. Therefore, the combination of references fails to teach or suggest all of the claim limitations of the present invention.

Furthermore, Applicant respectfully disagrees with the Examiner’s argument on page 5 of the Office action that because Kishi fails to disclose the cyclodextrin as complexed, then it must be uncomplexed. The question of whether the requisite suggestion or motivation is present cannot be resolved on the basis of subjective belief, unknown authority, or general conclusions about what is “basic knowledge” or “common sense.” *In re Lee*, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002).

Additionally, as acknowledged by the Examiner on page 4 of the Office Action, although Sorensen teaches mixtures of hydrocolloids, Sorensen does not teach cyclodextrin among the hydrocolloids. Applicant asserts that one skilled in the art would not substitute the cyclodextrin disclosed in Kishi for the hydrocolloid in Sorensen because Sorensen specifically discloses “according to the invention it has been found that the best mixture of hydrocolloids for use in the sealing material according to the invention is a mixture of approximately 36 parts by weight of sodium carboxymethyl cellulose to 16 parts by weight of guar gum” [column 7, lines 33-38]. These are not cyclodextrins as in the present invention, and Applicant asserts one skilled in the art would lack motivation to look outside of Sorensen for a cyclodextrin since it is not the most suitable nor is it listed as a potential suitable hydrocolloid. Furthermore, Applicant asserts that the suggested substitution is impermissible hindsight.

In light of the foregoing argument Applicant asserts that the present invention is not made obvious by Sorensen in view of Kishi under 103(a). Withdrawal of this rejection is earnestly solicited.

Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen et al. (US 4,67,732) in view of Kishi. The Examiner states it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a composition for adhesive barrier comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as taught by Poulsen, and replace one of the hydrocolloids in the hydrocolloid phase with 3-40% of cyclodextrin and apply the composition on a polyester substrate as taught by Kishi. Applicant respectfully disagrees.

A reference must be viewed as a whole, including portions that would lead away from the claimed invention. MPEP § 2141.03 (citing *W. L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983)).

Additionally, if the proposed modification would change the principles of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP § 2143.01 (citing *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959)).

Poulsen teaches away from utilizing a cyclodextrin as a component of a hydrocolloid composition unlike the present invention. As acknowledged by the Examiner on page 8 of the Office action, although Poulsen teaches mixture of hydrocolloids, the reference does not teach cyclodextrin among the hydrocolloids. Instead Poulsen discloses "suitable hydrocolloids are carboxymethyl celluloses and carboxymethyl starches and alkali metal derivatives, polyvinyl alcohol, gelatin, powdered pectin, vegetables gums, such as gum guar, gum Arabic....According to the invention sodium carboxymethylcellulose is preferred" [column 6, lines 41-51]. Poulsen fails to disclose that a cyclodextrin is a suitable type of hydrocolloid that may be utilized and one skilled in the art would assume that a cyclodextrin could not be used as the hydrocolloid in Poulsen. Therefore one skilled in the art would not substitute the cyclodextrin disclosed in Kishi in the invention of Poulsen because cyclodextrin is not listed as a suitable hydrocolloid for the composition disclosed in Poulsen and the utilization of a cyclodextrin would change the principle of operation of Poulsen. Applicant respectfully asserts that Poulsen in view of Kishi fails to render the present invention obvious under 103(a). Withdrawal of the rejection is earnestly solicited.

Furthermore, in performing the obviousness inquiry under 35 U.S.C. §103, the Examiner must avoid hindsight. "[O]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir. 1990). Applicant respectfully asserts the Examiner is utilizing hindsight by combining the cyclodextrin of Kishi with the composition of Poulsen when Poulsen explicitly states a preferred hydrocolloid which is not a cyclodextrin. Applicant respectfully asserts that Poulsen in view of

Kishi fails to render the present invention obvious under 103(a). Withdrawal of the rejection is earnestly solicited.

Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipman (WO 99/14282) in view of Kishi. The Examiner states it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an adhesive barrier or dressing for medical use comprising composition comprising continuoud rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as taught by Lipman, and replace one of the hydrocolloids in the hydrocolloid phase with 3-40% of cyclodextrin and apply the composition on a polyester substrate as taught by Kishi, Applicant respectfully disagrees for the same reasons as stated above in reference to Pouslen in view Kishi.

As acknowledged by the Examiner on page 11 of the Office action, although Lipman teaches mixture of hydrocolloids, the reference does not teach cyclodextrins among the hydrocolloids. Thus Applicant respectfully asserts one skilled in the art would not substitute the cyclodextrin disclosed in Kishi in the invention of Lipman because cyclodextrin is not listed as a suitable hydrocolloid for the composition disclosed in Lipman and the utilization of a cyclodextrin would change the principle of operation of Lipman. Additionally, Applicant asserts that the Examiner is utilizing hindsight to use a cyclodextrin within the composition disclosed in Lipman which is not allowable. Applicant respectfully asserts that Lipman in view of Kishi fails to render the present invention obvious under 103(a). Withdrawal of the rejection is earnestly solicited.

Lastly, Applicant respectfully directs the Examiner to take note that similar claims were granted in the European application (EP 1206290) which corresponds to the present application. Reference US 4,231,369 (Sorensen) which was cited by the Examiner in the present application was also a reference cited in the European application. The European application was deemed allowable over Sorensen in Europe and Applicant earnestly solicits an identical response from the Examiner in the U.S. regarding

this reference.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and an early Notice to that effect is earnestly solicited. The Examiner is encouraged to contact the undersigned in the event any small matters remaining outstanding so as to eliminate the necessity of another action and response.

If there are any fees associated with this communication, please charge said fees to Avery Dennison's Deposit Account No. 013025.

Respectfully submitted,
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